THE HONORABLE JOHN C. COUGHENOUR

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

RICHARD WEINSTEIN,

Plaintiff,

v.

ROBERT L. KIRKMAN, et al.,

Defendants,

and

ONCOTHYREON INC.,

Nominal Defendant.

CASE NO. C13-0769-JCC

ORDER GRANTING NOMINAL DEFENDANT'S MOTION TO DISMISS

This matter comes before the Court on Nominal Defendant Oncothyreon Inc.'s motion to dismiss (Dkt. No. 13). Having thoroughly considered the parties' briefing and the relevant record, the Court finds oral argument unnecessary and hereby GRANTS the motion for the reasons explained herein.

I. BACKGROUND

This is a shareholder derivative suit. Plaintiff Richard Weinstein currently holds stock in Nominal Defendant Oncothyreon Inc., and has done so since February 2007. (Dkt. No. 11 at 5.) Defendants Robert Kirkman, Julie Eastland, Christopher Henney, Richard Jackson, Daniel

Spiegelman, W. Vickery Stoughton, and Douglas Williams (collectively "Director Defendants") are current or former board members or officers of Oncothyreon. (*Id.* at ¶¶ 20–26.) Plaintiff alleges, on behalf of Oncothyreon, that the Director Defendants breached their fiduciary duties to shareholders, were unjustly enriched, abused their control over the company, and grossly mismanaged it. (*Id.* at 25–28.) Plaintiff alleges that a demand that the board pursue these claims would be futile and is therefore excused. (*Id.* at 24–25.) Oncothyreon moves to dismiss Plaintiff's amended complaint, arguing that demand is not excused and Plaintiff therefore lacks standing to bring a shareholder derivative suit. (Dkt. No. 13.)

Oncothyreon is a small biotechnology company incorporated in Delaware and headquartered in Seattle, Washington. (Dkt. No. 11 at ¶ 18.) It seeks to develop innovative cancer treatments. (*Id.* at ¶ 2.) It has no products on the market and has generated a profit during only one fiscal year. (*Id.* at ¶ 3.) The most advanced drug in Oncothyreon's development pipeline is L-BLP25 or Stimuvax, a cancer vaccine designed to stimulate the body's immune response to certain cancer cells. (*Id.* at ¶ 4; Dkt. No. 14-1 at 6.) Oncothyreon licensed L-BLP25 to Merck KGaA ("Merck").

Merck conducted the Phase 3[1] clinical trial relevant to this case ("START trial"). (Dkt. No. 11 at ¶ 5–7.) The START trial began in January 2007 and all data was collected by December 2012. (Dkt. No. 14-3 at 2.)[2] The START trial was a randomized, double-blind,

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[1] Phase 3 clinical trials test drugs on patients in a clinical setting. Successful completion of a Phase 3 clinical trial is typically the final step before submission to the FDA of an application to market a new drug. *See In re Adolor Corp. Sec. Litig.*, 616 F. Supp. 2d 551, 555 n.3 (E.D. Pa. 2009).

[2] Oncothyreon has filed a number of documents in support of its motion to dismiss. (Dkt. No. 14 and Dkt. No. 21.) Plaintiff made no motion to strike or other objection to the Court's consideration of any of those documents. On a motion to dismiss, the Court may consider documents referred to in the complaint or "any matter subject to judicial notice, such as SEC filings." *Dreiling v. Am. Express Co.*, 458 F.3d 942, 946 n.2 (9th Cir. 2006). The Court has considered the following documents: Document Nos. 14-1, 14-2, 14-5, 14-6, 14-7, 14-8, 14-9, and 14-10. Those documents are either referenced in Plaintiff's complaint, or are SEC filings, or

(footnote continued on next page)

placebo-controlled trial designed to show whether L-BLP25 improved survival rates of patients with advanced non-small cell lung cancer. (*Id.*) The START trial did not show a statistically significant improvement in the overall survival rate of patients treated with L-BLP25 versus those treated with a placebo. (Dkt. No. 11 at ¶ 7.) On December 19, 2012, after Oncothyreon issued a press release disclosing that the START trial failed to show that treatment with L-BLP25 improved non-small cell lung cancer survival rates, the company's stock price fell by over fifty percent and closed at $2.19 per share. (*Id.* at ¶ 9–10; Dkt. No. 14-8 at 6.) Oncothyreon's stock price fell to $1.97 per share in May 2013 after the company disclosed additional START trial data. (Dkt. No. 11 at ¶ 12; Dkt. No. 14-9.)

On August 13, 2012, Oncothyreon filed an amended Form 10-K (Form 10-K/A) with the SEC. (Dkt. No. 11 at ¶ 43; Dkt. No. 14-10.) The Form 10-K/A acknowledged that the company's Form 10-K for the year ending December 31, 2010 reflected an error in the company's calculation of the diluted earnings, or loss, per share. (Dkt. No. 14-10.) The amended form reflected a $0.72 loss per share for 2010, an increase over the previously reported $0.58 loss per share. (Dkt. No. 11 at ¶ 47.) In addition, the amended form reflected a $0.15 loss per share for the three months ending September 30, 2011, compared with previously reported earnings of $0.22 per share. (*Id.*) Oncothyreon reported that as a result of these errors, the company's "management had determined that there was a control deficiency in the company's internal control over financial reporting that constitutes a material weakness." (*Id.*)

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both. The Court has also considered Document No. 14-3, a clinical trial design document published on the National Institutes for Health's website at clinicaltrials.gov. *See Abely v. Aeterna Zentaris Inc.*, No. 12 Civ. 4711, 2013 WL 2399869, at *22 (S.D.N.Y. May 29, 2013) (it is appropriate to take judicial notice of clinical trial design documents published on the clinicaltrials.gov website).

II. DISCUSSION

A. Rule 23.1 Pleading Requirements

Federal Rule of Civil Procedure 23.1(b)(3) requires that a plaintiff bringing a shareholder derivative suit file a verified complaint that states "with particularity" whether a demand for the desired action has been made on the company's directors and the result of that effort, or the reason no demand was made. In a shareholder derivative suit, federal courts evaluate whether a demand to pursue the corporate claims raised in the suit would be futile under the law of the State of incorporation. *See Kamen v. Kemper Fin. Servs., Inc.*, 500 U.S. 90, 108–09 (1991); *Potter v. Hughes*, 546 F.3d 1051, 1055 (9th Cir. 2008). Oncothyreon is incorporated in Delaware. (Dkt. No. 11 at ¶ 19.) Accordingly, the Court applies Delaware law to determine whether Plaintiff has met the pleading standard for demand futility.

According to the Delaware Supreme Court, the demand requirement is "a recognition of the fundamental precept that directors manage the business and affairs of the corporation." *Aronson v. Lewis*, 473 A.2d 805, 814 (Del. 1984). But, directors who "are under an influence which sterilizes their discretion . . . cannot be considered proper persons to conduct litigation on behalf of the corporation." *Id.* In order to show demand futility, Delaware law requires that "under the particularized facts alleged, a reasonable doubt is created that: (1) the directors are disinterested and independent [or] (2) the challenged transaction was otherwise the product of a valid exercised of business judgment." *Id.*; *Brehm v. Eisner*, 746 A.2d 244, 256 (Del. 2000). Where a plaintiff alleges demand futility "in the absence of a business decision," "a court must determine whether or not the particularized factual allegations of a derivative stockholder complaint create a reasonable doubt that, as of the time the complaint is filed, the board of directors could have properly exercised its independent and disinterested business judgment in responding to a demand." *Stone v. Ritter*, 911 A.2d 362, 367 (Del. 2006) (quoting *Rales v. Blasband*, 634 A.2d 927, 934 (Del. 1993)). The court draws all "reasonable factual inferences that logically flow from the particularized facts alleged, but conclusory allegations are not

considered as expressly pleaded facts or factual inferences." *Brehm*, 746 A.2d at 255.

There were six directors on Oncothyreon's board when this suit was filed: Kirkman, Henney, Jackson, Spiegelman, Stoughton, and Williams. (Dkt. No. 11 at 24–25.) Spiegelman, Stoughton, and Williams were also members of the board's Audit Committee. (Dkt. No. 11 at ¶ 56(b).) In order to establish demand futility, Plaintiff must plead particularized facts that create a reasonable doubt that at least three of the six directors could exercise independent business judgment in responding to a demand. *Beam v. Stewart*, 845 A.2d 1040, 1046 n.8 (Del. 2004) (with an even number of directors, plaintiff must show that at least half of the directors are not disinterested). Plaintiff argues that there is at least a reasonable doubt as to whether the board members are independent for purposes of responding to a demand because the board members face a "substantial likelihood" of liability based on Plaintiff's allegations that they issued false or misleading statements regarding the progress of the START trial. (Dkt. No. 19 at 14–15.) Plaintiff asserts that this is particularly true of the three Audit Committee members, who had an obligation to review "financial statements" and "earnings press releases and guidance prior to their issuance." (Dkt. No. 19 at 16–21.)

Under Delaware law, "[d]emand is not excused solely because the directors would be deciding to sue themselves." *In re Citigroup Inc. S'holder Derivative Litig.*, 964 A.2d 106, 121 (Del. Ch. 2009). The "mere threat of personal liability" standing alone, is "insufficient to challenge either the independence or disinterestedness of directors." *Aronson*, 473 A.2d at 815. Instead, a plaintiff must show there is a "substantial likelihood of director liability." *Id.*

B. START Trial Results

Based on the particularized factual allegations in Plaintiff's complaint, and the reasonable inferences to be drawn from them, there is no "substantial likelihood" that Oncothyreon's directors could be personally liable. Plaintiff's theory is essentially that the Director Defendants knew that the START trial would fail to establish L-BLP25's effectiveness in increasing cancer survival rates before the data collection process was completed in December of 2012. (*See, e.g.*,

Dkt. No. 11 at ¶ 7 ("defendants failed to disclose that the clinical trials of L-BLP25 were not proceeding according to plan"); Dkt. No. 19 at 19 ("this Court can reasonably infer at the pleading stage that the Audit Committee Defendants, if not all the Demand Directors, knew or should have known long prior to December 19, 2012 that L-BLP25 was not achieving its main goal – improving overall survival of lung cancer . . . .").) Plaintiff's theory appears to be based on the fact that the START trial provided for two "interim looks" at the data by an Independent Data Monitoring Committee ("IDMC"). (*See* Dkt. No. 14-3 at 1, 14-4.[3]) At each look, the IDMC reviewed the data to determine whether the START trial should be stopped either because: (1) the data established that L-BLP25 was effective and therefore continued administration of a placebo to some study participants would be inappropriate; or (2) the data established that there was no possibility that L-BLP25 was effective in treating cancer and continued administration of the drug would therefore be unethical. (*Id.*) The IDMC conducted the two interim looks in December of 2010 and March of 2012 and concluded that the START trial should continue. (*Id.*) Oncothyreon reported those conclusions in press releases and Form 8-Ks filed with the SEC. (Dkt. Nos. 14-5, 14-6.) Oncothyreon also reported the results of the interim looks in its 2011 Annual Report to Shareholders. (Dkt. No. 14-4 at 4.)

The inference that Plaintiff asks the Court to draw is that either Merck—the company conducting the START trial—or the IDMC reported details about the progress of the trial to Oncothyreon or the board. That inference is not reasonable because it fundamentally misunderstands the purpose of an independent interim review of an ongoing clinical trial.

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[3] The Court has considered the information regarding the START trial's "interim looks" contained in Oncothyreon's 2011 Annual Report to Shareholders (Dkt. No. 14-4). That Report is not referenced in Plaintiff's complaint. Without information about the interim looks, however, Plaintiff's argument is essentially that Oncothyreon's board must have known the results of a double-blind clinical trial being conducted by third-party before the trial was complete. To the extent that Plaintiff is making that argument, it is not supported by any facts, is illogical, and is rejected.

According to the FDA's guidance for industry on statistical principles for clinical trials, "The independence of the IDMC is intended to control the sharing of important comparative information and to protect the integrity of the clinical trial from adverse impact resulting from access to trial information." Food & Drug Admin., *Guidance for Industry, E9 Statistical Principles for Clinical Trials* § 4.6 (1998), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073137.pdf. In other words, the purpose of having an *independent* data monitoring committee is to protect the validity of the double-blind trial results by avoiding disclosure of trial data to the sponsors and investigators prior to the trial's completion. *See In re Columbia Labs., Inc. Sec. Litig.*, 144 F. Supp. 2d 1362, 1370 (S.D. Fla. 2001) ("In light of the fact that the study was double-blind, the administrators of the study, the subjects in the study, and Defendants could not have been aware of the eventual results of the UNAIDS study before it had been completed.")

The Court recognizes that in at least one case, a purportedly independent data monitoring committee disclosed data to the trial sponsor. *See In re Northfield Labs., Inc. Sec. Litig.*, No. 06-C-1493, 2008 WL 4372743 (N.D. Ill. Sept. 23, 2008) ("In the second amended complaint, plaintiffs allege that in November 1999, the ANH trial's independent data monitoring committee provided the study data to Northfield and that Northfield itself conducted the analysis that determined that the PolyHeme group suffered adverse events at a higher rate than the control group. This makes it clear that Northfield knew that at least some of the results of the ANH trial were negative."). Here, however, Plaintiff has not specifically alleged that the IDMC disclosed START trial data to Oncothyreon or Merck, or alleged any particularized facts to support such a claim. The Court cannot reasonably infer that START trial data was disclosed to the board based solely on the importance of L-BLP25 to Oncothyreon's financial prospects because such a disclosure would defeat the purpose of an independent committee and potentially undermine the usefulness of the START trial in obtaining regulatory approval to market L-BLP25. The Court

does not see any reason to conclude that Audit Committee members, whose primary function is to oversee financial affairs, would have had unique access to information about the START trial.

In arguing to the contrary, Plaintiff relies heavily on *In re Biopure Corporation Derivative Litigation*, 424 F. Supp. 2d 305 (D. Mass. 2006). In *Biopure*, the Court found it appropriate to infer that the directors of a biotechnology company would have had knowledge of the FDA's clinical hold on its lead product. *Id.* at 307–308. The Court agrees with Judge Gertner's conclusion. Inferring knowledge of a significant adverse regulatory action, however, is not at all similar to inferring advance knowledge about data being collected in an ongoing clinical trial. The only similarity between this case and *Biopure* is that both cases relate to a biotechnology company's lead product.

Plaintiff argues that Director Defendant Kirkman necessarily lacked independence because he is also the President and CEO of Oncothyreon and has a substantial financial stake in maintaining his current office. Even if that is true, however, Plaintiff has failed to put forward any particularized facts to support the conclusion that at least two of the five remaining directors lacked independence for purposes of considering a litigation demand.

Finally, in considering whether the Director Defendants face a substantial likelihood of liability, the Court has considered the statements Oncothyreon and its board made about the prospects for regulatory approval and marketing of L-BLP25. Many of those statements are reproduced in Plaintiff's complaint. In a March 2011 Form 10-K filed with the SEC, the Director Defendants made the following statements:

> Our near-term success is highly dependent on the success of our lead product candidate, Stimuvax, and we cannot be certain that it will be successfully developed or receive regulatory approval or be successfully commercialized.
>
> . . . .
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> . . . . Clinical trials involving the number of sites and patients required for FDA approval of Stimuvax may not be successfully completed. If these clinical trials fail to demonstrate that Stimuvax is safe and effective, it will not receive regulatory approval. Even if Stimuvax receives regulatory approval, it may never be successfully commercialized. If Stimuvax does not receive regulatory approval or is not successfully commercialized . . . we may not be able to generate revenue,

become profitable or continue our operations.

(Dkt. No. 11 at ¶ 36.) Plaintiff alleges that because the Director Defendants "routinely warned about the status of L-BLP25, they likewise were under a heightened duty to timely and accurately disclose information concerning it." (Dkt. No. 11 at ¶ 37.) That may be true, but the warnings clearly told investors that the company's future was closely tied to the outcome of ongoing clinical trials, the results of which it was impossible to predict. Investing in a biotechnology start-up like Oncothyreon involves a certain amount of risk that the company's drugs will not be proven effective or be approved for marketing. *See In re Adolor Corp. Sec. Litig.*, 616 F. Supp. 2d at 570. In this case the risk did not payoff. That does not mean that the company's directors are to blame.

For all of the foregoing reasons, demand is not excused based on Plaintiff's theory that the Demand Directors failed to disclose information related to the START trial.

C. Accounting Errors

Plaintiff's complaint describes accounting errors reflected in Oncothyreon's filings with the SEC. (Dkt. No. 11 at ¶ 47.) Oncothyreon argues that those allegations are insufficient to excuse demand because they are not supported by any claim or particularized factual allegations that the Director Defendants were aware of the accounting errors when they authorized filing the original Form 10-Ks. *See Guttman v. Huang*, 823 A.2d 492, 504 (Del. Ch. 2003) (dismissing complaint because demand was not excused where "[n]othing in the complaint provides any particularized basis to infer that these outside directors had any idea about the questionable accounting practices"). Plaintiff has not responded to this argument and has therefore waived any response he may have.

Moreover, Plaintiff's complaint contains no allegation that the company or its shareholders were harmed by the accounting errors. After the board voluntarily reported the errors to the SEC and the public, there was no immediate or significant decline in the value of the company's stock. (Dkt. No. 14-11) (table showing Oncothyreon closing prices during August

of 2012, which increased after the Form 10-K/A was filed on August 13, 2012).[4] In addition, the corrections had "no impact on [Oncothyreon's] consolidated balance sheets, net income or (loss), basic earnings (loss) per share, or the consolidated statements of cash flows or stockholders' equity" for any of the periods covered by the corrections. (Dkt. No. 11 at 20; Dkt. No. 14-10 at 3.) Plaintiff's complaint fails to set forth any basis to conclude that demand should be excused based on the alleged accounting errors.

III. CONCLUSION

For the foregoing reasons, Oncothyreon's motion to dismiss (Dkt. No. 13) is GRANTED. Plaintiff has provided the Court with no basis to conclude that its demand allegations could be saved by amendment. Accordingly, Plaintiff's amended complaint (Dkt. No. 11) is DISMISSED with prejudice and without leave to amend. The Clerk is respectfully directed to CLOSE this case.

DATED this 16th day of September 2013.

John C. Coughenour
UNITED STATES DISTRICT JUDGE

[4] The Court may take judicial notice of Oncothyreon's historical stock prices in ruling on a motion to dismiss under Rule 23.1. *In re F5 Networks, Inc. Derivative Litig.*, No. C06-0794-RSL, 2007 WL 2253382, at *1 (W.D. Wash. Aug. 1, 2007).